UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

JOSEPH BARONE,	:	
	:	Index No. 6:17-cv-06877
Plaintiff,	:	
	:	
-against-	:	
	:	
	:	
BAUSCH & LOMB, INC., MORCHER GmbH, and FCI OPHTHALMICS, INC.,	:	
	:	
	:	
	:	
Defendants.		

PLAINTIFF'S MEMORANDUM OF LAW
IN OPPOSITION TO SUBJECT MATTER JURISDICTION
AND IN SUPPORT OF REMANDING THE CASE

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Pursuant to the Court's August 27, 2018 Order (R. Doc. 31), plaintiff submits this Memorandum of Law in opposition to subject matter jurisdiction and in support of remanding the case back to New York Supreme Court, County of Monroe.

I. FACTUAL/PROCEDURAL BACKGROUND

This action seeks redress for the injuries sustained and the pain and suffering endured by Joseph Barone as a direct result of the failure of Bausch & Lomb, Inc.'s (B&L's) Crystalens AO Lens product ("Crystalens") and Morcher GmbH's and FCI Ophthalmics, Inc.'s Capsular Tension Ring. The Crystalens and the Capsular Tension Ring product were implanted in Mr. Barone's right eye on or about August 20, 2015 in order to, *inter alia*, improve his eyesight. Plaintiff's Amended Complaint maintains causes of action for strict liability and negligence based on B&L's failure to report to the FDA instances of "Z syndrome," a known defect in the Crystalens. Plaintiff's Amended Complaint also maintains causes of action for strict liability, negligence, and breach of warranties against Morcher and FCI in connection with the failure of the Capsular Tension Ring.

On December 20, 2017, B&L removed the matter under 28 U.S.C. § 1331. On August 27, 2018, the court issued an Order directing the parties to file briefing as to subject matter jurisdiction.

II. PRELIMINARY STATEMENT

Federal district courts "have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. Federal question jurisdiction pursuant to § 1331 is typically invoked in cases in which the plaintiff "pleads a cause of action created by federal law." *Grable & Sons Metal Prods. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 125 S. Ct. 2363 (2005). State law causes of action may nonetheless be considered to

arise under federal law for purposes of federal question jurisdiction if the conjunctive, four-pronged *Grable-Gunn* test is met. This test provides that a court will have federal question jurisdiction over a state law claim "if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn v. Minton*, 568 U.S. 251, 258 (2013). As the Supreme Court stated, "all" of the four requirements must be met for jurisdiction to be proper. Id at 258. Indeed, only a "special and small category" of cases satisfies the test. *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 701 (2006)). And, "the mere presence of a federal issue in a state cause of action does not automatically confer federal-question jurisdiction." *Merrell Dow Pharms., Inc. v. Thompson*, 478 U.S. 804, 813, 106 S. Ct. 3229, 92 L. Ed. 2d 650 (1986); *Finance & Trading, Ltd. v. Rhodia S.A.*, 2004 U.S. Dist. LEXIS 24148, 2004 WL 2754862, at *6 (S.D.N.Y. 2004); *Cleanup N. Brooklyn v. Brooklyn Transfer LLC,* No. 17-cv-05621 (NG) (RER), 2018 U.S. Dist. LEXIS 71256, at *3 (E.D.N.Y. Apr. 26, 2018). As set forth in detail below, three of the four prongs cannot be satisfied and thus remand is appropriate.

Plaintiff brings his claims not under federal law, but rather for violation of the parallel requirements of New York common law. In its brief in support of subject matter jurisdiction, B&L omits any reference to *Baker v. St. Agnes Hosp.,* 70 A.D.2d 400, 421 N.Y.S.2d 81 (App. Div. 1979), and B&L argues there is no New York common law duty at issue, only an alleged violation of a federal reporting requirement. R. Doc. 38, p. 2. But, *Baker* (which was raised in plaintiff's 12(b)(6) briefing and which was emphasized during oral argument) makes it clear that plaintiff's Amended Complaint pleads claims for breaches of duties under New York law, which do not impose any requirements "different from, or in addition to" duties under federal law. In that case, the mother of an infant injured by defendant's drug filed an action seeking damages

from the drug manufacturer on theories of common law strict liability and negligence. Defendant argued that its package inserts adequately warned of the drug's dangers and that the doctor's failure to consult reference material on the drug before prescribing it was the proximate cause of the infant's injuries. The Appellate Division denied defendant's motion for summary judgment and indicated that under New York common law, a drug manufacturer is "under a duty to warn the medical profession of dangers inherent in its biological drugs which, in the exercise of reasonable care, it knew or should have known to exist." And, "it must keep abreast of knowledge of its products as gained through research, adverse reaction reports, scientific literature and other available methods;" and "equally important, it must take such steps as are reasonably necessary to bring that knowledge to the attention of the medical profession. The greater the potential hazard of the drug, the more extensive must be the manufacturer's efforts to make that hazard known to the medical profession." Id. at 82. The *Baker* court also provided examples of what defendant could have done to discharge its duty under New York common law, i.e. "dear Doctor" letters addressed to physicians, notices in medical journals, and calling physicians personally to present them with information. Id. at 86.

Thereafter, in *Rosen v. St. Jude Med., Inc.,* 41 F. Supp. 3d 170 (N.D.N.Y. 2014), where plaintiff alleged that she suffered injuries as a result of defects associated with a Class III medical device and plaintiff asserted a failure to warn claim, the Court cited *Baker* to describe the duty of a medical device manufacturer under New York common law. The Court then held as follows:

> Plaintiff alleges that Defendants failed to comply with FDA reporting requirements, including 21 C.F.R. § 803.50, and that because Defendants violated the FDCA, they are subject to state law liability. Plaintiff points out that the FDA publishes adverse events and MDRs in a public, searchable database called the Manufacturer and User Facility Device Experience ("MAUDE"), which physicians and the general public may access to view safety data on medical

> devices. Thus, Plaintiff argues that Defendants' failure to timely report to the FDA led to a violation of state law, in that Defendants also did not exercise reasonable care in informing the medical community of known risks. Because Plaintiff has alleged a violation of a federal regulation, and New York imposes a similar state duty…the Court finds that Plaintiff's failure to warn claim is "parallel" and not "different or in addition to" the applicable requirements under federal law. Id. at 185 (internal quotes and citations omitted).

In the case at bar, plaintiff is simply asserting that had B&L complied with 21 CFR § 803.50 by communicating adverse event reports to the FDA, B&L would have effectively warned surgeons, including plaintiff's surgeon, of those adverse events. This is because events which are reported to the FDA are input into the MAUDE system, which is available to medical professionals and the public at large. B&L's failure to communicate adverse event reports to the FDA -- which was required under federal law -- amounted to a breach of the parallel, state common law duty.

Though neither Morcher nor FCI filed motions to dismiss and instead answered the Amended Complaint, these defendants use their joint brief to generally assert that plaintiff's claims against them are preempted. This is incorrect. To be clear, plaintiff's causes of action against Morcher and FCI are grounded in state common law. But, in any event, at the close of discovery, defendants will have the opportunity to challenge the extent to which plaintiffs can establish through competent evidence that, *inter alia*, the product defects resulted from violations of federal regulations, approved processes and procedures were not followed, and plaintiff's injury was caused by this deviation.

Morcher and FCI write that they "join in and incorporate" B&L's brief "as if set forth in full herein," and Morcher and FCI state that "for all the reasons stated therein" the court should exercise subject matter jurisdiction. (R. Doc. 39, p 2 of 10). Accordingly, Morcher's and FCI's subject matter jurisdiction argument rises or falls with B&L's brief.

III. LEGAL ARGUMENTS

As set forth by the 2nd Circuit in *Blockbuster, Inc. v. Galeno*, 472 F.3d 53, 57 (2d Cir. 2006), "it is well-settled that the party asserting federal jurisdiction bears the burden of establishing jurisdiction." Further, "removal statutes are to be strictly construed" and "all doubts should be resolved in favor of remand." See, e.g. *Miller v. First Sec. Invs., Inc.,* 30 F. Supp. 2d 347, 350 (E.D.N.Y. 1998). Defendants cannot meet their burden for establishing jurisdiction and thus remand is necessary.

Again, the *Grable-Gunn* test provides that a court will have federal question jurisdiction over a state law claim "if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn*, 568 U.S. 251, 258.

Plaintiff's Amended Complaints asserts only state law causes of action, all of which seek compensation for injuries plaintiff sustained as a result of failures of the Crystalens and the Capsular Tension Ring. Pursuant to the Medical Device Amendments of 1976, 21 U.S.C. § 360c et seq. (the "MDA"), state law claims concerning Class III medical devices are expressly preempted by federal law if they seek to impose requirements that are "different from, or in addition to" those imposed by federal law. *Riegel v. Medtronic, Inc*., 552 U.S. 312, 321 (2008) (quoting 21 U.S.C. § 360k(a)(1)). The MDA's express preemption provisions "do[] not , [however,] prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations; when the state duties in such a case 'parallel,' rather than add to, federal requirements." Id. at 330 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)). In view of these preemption principles, plaintiff has pled federal requirements that "parallel" the state law duties on which he bases the state law claims. So, plaintiff concedes for purposes of this

subject matter jurisdiction brief only that issues of federal law are raised by plaintiff's state law claims. The other three prongs of the *Grable-Gunn* test cannot be met, however, and so remand is appropriate.

A. "The Second *Grable-Gunn* Prong Cannot be Satisfied Because the Federal Issue is not Actually Disputed"

In *MHA, LLC v. UnitedHealth Grp., Inc.,* 2014 U.S. Dist. LEXIS 7035 (D.N.J. Jan. 21, 2014), the court rejected defendant's argument that a federal issue was actually disputed and explained that there can be no finding of an "actual dispute" unless interpretation of a federal statute is required. Similarly, in *MHA LLC v. Healthfirst, Inc.,* 629 F. App'x 409, 414 (3rd Cir. 2015), the court rejected defendant's argument that a federal issue was "actually disputed" because defendant had "not identified a dispute over the meaning of particular statutory text." Moreover, in *Congregation Machna Shalva Zichron Zvi Dovid v. United States Dep't of Agric.,* 557 F. App'x 87, 90 (2nd Cir. 2014), the Second Circuit remanded, ruling that "the determination at issue here is a fact-specific application of the regulations to [plaintiff] that does not implicate the *validity* of the regulations themselves, or have any other broader effect on federal interests." (emphasis added). See also *McLaughlin v. Bayer Essure, Inc.,* No. 18-1144 , 2018 U.S. Dist. LEXIS 122280, at *18 (E.D. Pa. July 23, 2018) (remanding the case and explaining "Bayer has simply not established that there is an actual disagreement about an interpretation of federal law that is material to the claims at issue."); *Taylor v. Bank of Am., N.A.,* No. 3:18-cv-00288-MOC-DSC, 2018 U.S. Dist. LEXIS 146774, at *5 (W.D.N.C. Aug. 29, 2018) (remanding the case and explaining "plaintiffs' Complaint does not raise any disputes as to the meaning of a particular statutory text.")

The sole argument advanced by defendant as to whether there is an actual dispute of a federal issue is: "Plaintiff alleges B&L violated 21 CFR § 803.50(a) and that such violation

caused or contributed to his injuries. B&L denies that it violated 21 CFR § 803.50(a) and further denies that any alleged violation could have caused plaintiff's injuries. This is the primary, if not the sole, matter at issue." R. Doc.38, p. 14. Thus, B&L effectively concedes that the dispute is not over statutory interpretation or the validity of the regulations, but instead involves the kind of fact-specific disputes that militate against finding that a federal issue is "actually disputed" for subject matter jurisdiction purposes.

Moreover, B&L's cite to an excerpt from *Gunn*[1] (R. Doc. 38, p. 14) undermines its argument. This is because: 1) the *Gunn* Court remanded the case; and 2) a plain reading of the opinion reveals that the case involved a dispute as to the statutory interpretation of the "on sale" bar, i.e. 35 U.S.C. §102(b), and whether Plaintiff asserting the so-called "experimental use exception" to the "on sale" bar on Defendant's behalf would have necessarily allowed Defendant to prevail in his federal patent infringement case. Here, it is beyond dispute that B&L was obligated to report adverse events, and so, unlike in *Gunn,* there is no need for the Court to resolve differing interpretations of 21 CFR §803.50. B&L's reference (R. Doc. 38, p. 14) to *Broder v. Cablevision Sys. Corp*., 418 F.3d 187 (2d Cir. 2005) also undermines its argument. Indeed, the *Broder* Court only found that a federal issue was actually disputed because: "Cablevision maintains that its provision of Winter Season rates did not violate the § 543(d) uniform rate requirement. Cablevision contests, *inter alia*, whether Broder and the class members subscribed in areas that lacked 'effective competition,' and whether the Winter Season rates are exempt from the § 543(d) uniformity requirement as promotional rates. These questions

[1] "The federal issue is also 'actually disputed' here—indeed, on the merits, it is the central point of dispute. Minton argues that the experimental-use exception properly applied to his lease to Stark, saving his patent from the on-sale bar; petitioners argue that it did not." *Gunn*, 568 U.S. at 259

involve aspects of the complex federal regulatory scheme applicable to cable television rates…"[2] Again, this is distinguishable from the instant matter given that the Court is not called upon to resolve disputes as to the meaning of a federal statutory text or as to the validity of a federal statute or regulation.

B&L concedes there is no dispute as to the *interpretation* of 21 C.F.R. § 803.50, but that the dispute is as to whether that provision was violated and as to whether a violation could have caused the injuries. These are merely fact-specific issues arguably necessitating determinations about whether B&L should have reported the adverse events, whether B&L did report the adverse events, and whether B&L's failure to report the adverse events be causally linked to the injury. Accordingly, remand is appropriate in this case.

B. The Third *Grable-Gunn* Prong Cannot be Satisfied Because the Federal Issue is Not Substantial

B&L advances the disingenuous argument that "determination of plaintiff's claims of failure to report adverse events involving the subject device, wherever and whenever they occurred prior to plaintiff's surgery, would have a [] nationwide impact." R. Doc. 38, p. 21. B&L also argues that "the implications of the claim here…will apply…to the entire regulatory scheme that governs reporting requirement for all medical devices." Id. at p. 20.

These assertions are completely at odds with the actual text of the Amended Complaint, which simply asserts that when B&L failed to submit Adverse Reaction reports in violation of 21 C.F.R. § 803.50, it also violated New York common law. (R. Doc. 1-2, p. 195). There is no

[2] Moreover, *Broder* was decided without the benefit of *Gunn*, which clarified the substantiality prong of the *Gunn-Grable* test. See *Mihok v. Medtronic, Inc.,* 119 F. Supp. 3d 22, 33 n.6 (D. Conn. 2015) (distinguishing *Broder*, in part, because it was "decided before the Supreme Court's decision in *Gunn*); *See Knox v. Mazuma Credit Union*, No. 15-0288-CV-W-ODS, 2015 U.S. Dist. LEXIS 68183, 2015 WL 3407618, at *3 n. 1 (W.D. Mo. May 27, 2015) (distinguishing *Broder*, in part, because it was decided before the Supreme Court's decision in *Gunn*).

logical basis for arguing that this limited claim impacts the entire regulatory scheme or has a broad, nationwide impact. Indeed, plaintiff's claim is analogous to the claim in *Mihok v. Medtronic, Inc.,* 119 F. Supp. 3d 22 (D. Conn. 2015), where plaintiff alleged defendant violated various provisions of the Current Good Manufacturing Practice regulations promulgated under the FDCA and by virtue of those violations, defendants violated the Connecticut Products Liability Act. In remanding the case to state court, the *Mihok* court explained its rationale for rejecting the same arguments advanced by B&L:

> The court's analysis of the FDA regulations will take the form of a highly fact-specific application of the regulations to Medtronic's conduct that is unlikely to substantially impact the federal system. For instance, Plaintiffs cite a violation of 21 C.F.R. § 820.30(c) where design input work for [Medtronic's] 8731 Intrathecal Catheter has not resulted in development of a complete design specification for the Platinum/Iridium (Pt/Ir) catheter tip bond. It is difficult to see how determinations concerning these and similarly discrete allegations would substantially impact the federal system. That the application of the regulations may require a state court to grapple with federal law and perform an individualized assessment of both the scope of the federal regulation at issue and the particular conduct alleged to fall within (or without) that regulation is not alone sufficient to warrant federal jurisdiction…State courts are more than competent to interpret federal regulations and thus, a state law cause of action that requires the interpretation of a federal regulation, by itself, is not sufficiently substantial' to create federal jurisdiction. Id at 31-32. (internal cites and quotations omitted).

Thus, B&L's assertions (R. Doc. 38, p. 16) that the Court will somehow need to step into the shoes of the FDA to make determinations about adverse event reporting requirements and MAUDE are unavailing. Similarly, in *Carmine v. Poffenbarger,* 154 F. Supp. 3d 309 (E.D. Va. 2015), plaintiff alleged state products liability and medical malpractice claims arising from implantation of defendant's device in plaintiff's spine, and the Court remanded the case because "the federal issues in dispute here, while important to the individual litigants, are not significant to the federal system as a whole." See also *Boerhinger v. Smith & Nephew, Inc*., No. 18cv920 (WWE), 2018 U.S. Dist. LEXIS 169996 (D. Conn. Oct. 2, 2018), (remanding the case and

explaining the substantiality prong was not satisfied because "analysis of the federal regulations and standards relevant to plaintiff's state product liability claims will require a fact-specific analysis of those regulations and standards that will be unlikely to substantially impact the federal system or medical device manufacturers nationwide.") (internal quotes and citations omitted). Defendant cannot meaningfully distinguish *Mihok*, *Carmine*, or *Boeringer*.

The fact that there is no private right of action under the FDCA further demonstrates that the federal issues raised in this case are not "substantial." See 21 U.S.C. 337(a) ("Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."). As the court explained in *Antonetti v. Woodhull Med. & Mental Health Ctr. (HHC),* 2014 U.S. Dist. LEXIS 116363, at *13 n.9 (E.D.N.Y. July 28, 2014) (Report & Recommendation Adopted), which found no subject matter jurisdiction:

> …Even if plaintiff's complaint can be construed as raising an issue of law involving the MDA, the Court lacks federal question jurisdiction over plaintiff's complaint. In discussing the FDCA, the same statute at issue here (as amended by the MDA), the Court in *Merrell Dow Pharm. Inc. v. Thompson,* 478 U.S. 804, 813 (1986), held that "a complaint alleging a violation of a federal statute as an element of a state cause of action, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim 'arising under the Constitution, laws, or treaties of the United States.'" *Merrell Dow*, 478 U.S. at 817. While the Supreme Court clarified in *Grable* that *"Merrell Dow* should be read in its entirety as treating the absence of a federal private right of action as evidence relevant to, but not dispositive of, the "sensitive judgments about congressional intent" that § 1331 requires," the Court did not overturn the holding in *Merrell Dow* that the Court lacked federal question jurisdiction in that case given "the strength of the federal interest at stake and the implications of opening the federal forum." *Grable*, 545 U.S. 308, 318, 125 S. Ct. 2363, 162 L. Ed. 2d 257.

Similarly, in *Goade v. Medtronic, Inc.,* No. 13-5123-CV-SW-ODS, 2013 U.S. Dist. LEXIS 169961 (W.D. Mo. Dec. 3, 2013), where the Court remanded the case, the Court explained that Congress has not created a federal right of action under the FDCA, nor has it preempted the

entirety of state regulation, or divested state courts of jurisdiction in such matters. The *Goad* Court held that this failure to create a private right of action under the FDCA "cements the Court's conclusion that the federal issues raised in the complaint are not substantial." A similar result is warranted here.

C. The Fourth *Grable-Gunn* Prong Cannot be Satisfied Because Exercising Federal Jurisdiction in the Case will Disturb the Congressionally-Approved Balance of Federal and State Judicial Requirements

The lack of a private right of action under the FDCA also prevents B&L from satisfying the fourth prong of the *Grable-Gunn* analysis. In *Steed v. Bos. Sci. Corp.*, 2017 U.S. Dist. LEXIS 107904 *9 (N.D. Ohio July 12, 2017), where plaintiff brought a complaint premised on strict liability theories against a Class III medical device manufacturer, the court held that exercising jurisdiction would upset the federal-state balance approved by Congress because, *inter alia*, Congress has not provided a private right of action under the FDCA. See also *Mauk v. Medtronic, Inc.*, 41 F. Supp. 3d 654 (W.D. Ky. 2014) (where plaintiff brought strict liability claims against a Class III medical device manufacturer, the Court remanded the case and explained even if plaintiffs' complaint presented substantial federal issues, the resolution of this dispute in federal court will disrupt the federal-state balance approved by Congress given that "Congress chose to neither permit federal jurisdiction, nor completely preclude state jurisdiction, over claims alleging violations of the MDA. Further, the Supreme Court in *Merrell Dow* indicated its unwillingness to open up federal courts to all state law tort claims involving medical devices.") And, in *Johnson v. Bayer Healthcare, LLC,* 2017 U.S. Dist. LEXIS 195564 (E.D. Mo. Nov. 29, 2017) the Court held there is no "federal cause of action under the FDCA" and "accepting federal jurisdiction in a medical device products liability case…would disrupt the

federal-state balance contemplated by Congress." Similarly, in the case at bar, exercising subject matter jurisdiction over plaintiff's state tort law claims would disturb the federal-state balance.

B&L ignores these cases and instead cites to *Burrell v. Bayer Corp.,* No. 1:17-cv-00032-MOC-DSC, 2017 U.S. Dist. LEXIS 38770 (W.D.N.C. Mar. 17, 2017) where the court found that by virtue of passing the MDA, it necessarily would not upset the federal-state balance to have medical device claims remain in federal court. But, this logic has been soundly rejected by multiple courts. See, e.g. *Antonetti v. Woodhull Med. & Mental Health Ctr. (HHC),* 2014 U.S. Dist. LEXIS 116363, at *13 n.9 (E.D.N.Y. July 28, 2014) (Report & Recommendation Adopted) (interpreting *Merrell Dow Pharm. Inc. v. Thompson* differently than the *Burrell* court interpreted it and finding no subject matter jurisdiction); See also *Steed,* 2017 U.S. Dist. LEXIS 107904, at *7 n.5 (rejecting *Burrell* and explaining that the *Burrell* Court failed to consider the refined substantiality standard announced in *Gunn*). This Court should similarly reject *Burrell* and hold that resolution of this dispute would disrupt the federal-state balance approved by Congress.

IV. CONCLUSION

In order for defendants to demonstrate that subject matter jurisdiction is proper, defendants must show that each of the four *Grable-Gunn* requirements has been satisfied. Defendants fall far short of this burden. Indeed, as set forth above, three of the four requirements cannot be satisfied. Accordingly, the court should remand the case back to New York Supreme Court, Monroe County.

DATED: October 8, 2018

Respectfully submitted,
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